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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/883,093	06/14/2001	Catherine Guenther	R-126	7936

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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	12

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Application No.	Applicant(s)
09/883 093	GUENTHER ET AL
Examiner	**Art Unit**
Michael C Wilson	1632

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1 136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35, 37 and 38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

DETAILED ACTION

The amendment filed 11-7-02, paper number 9, requesting replacement of Fig. 2A has not been entered. The amendment was not entered because enclosed new Fig. 2A did not have bracketing of nucleic acids found in original Fig. 2A and because a marked up version of the changes was not provided.

The amendment filed 12-11-02, paper number 11, was entered in part. The amendment to pg 8, lines 12-15, has been entered. The amendment to Fig. 2A has not been entered because the clean copy of Fig. 2A did not have bracketing of nucleic acids found in original Fig. 2A and because the clean copy and marked up copy of Fig. 2A do not match (the clean copy does not have bracketing while the marked up copy does have bracketing).

Sequence Listing

The application is in sequence compliance because the nucleotide sequence of Fig. 2A has been described in the amendment to pg 8, line 12-15, filed 12-11-02.

Election/Restrictions

Claim 36 has not been considered because it is unclear. Determining whether an agent modulates an abnormal spleen, thymus or lymph node using cells as claimed in the absence of an animal does not make sense. As such, a determination as to what group claim 36 belongs cannot be made. Therefore, claim 36 has been excluded from consideration in the restriction requirement.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 1-4, drawn to a construct encoding two nucleic acid sequences homologous to a nuclear hormone receptor gene and a selectable marker, classified in class 435, subclass 320.1.

Group II, claims 5-7, 9, 13-15, 31 and 35, drawn to cells transfected with a vector encoding two nucleic acid sequences homologous to a nuclear hormone receptor gene and a selectable marker, cells having a disruption in a nuclear hormone receptor gene, cells isolated from a mouse having a disruption in a nuclear hormone receptor gene, and ES cells having a disruption in a nuclear hormone receptor gene, methods of using such cells to test agents, classified in class 435, subclass 325.

Group III, claims 8, 11, 12, 17-29, 32-34 and 38, drawn to a transgenic mouse having a disruption in a nuclear hormone receptor gene and a method of making such a mouse, classified in class 800, subclass 8.

Group IV, claims 10 and 30, drawn to a method of making transgenics having a disruption in a nuclear hormone receptor gene, classified in class 800, subclass 21.

Group V, claims 16 and 37, drawn to an agent that modulates a nuclear hormone receptor, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the cells of group II can be used to test cells *in vitro* while the construct can be used to make a probe. The cells do not require the construct and the construct does not have to be used to make the cells as they may occur naturally or by other means of mutagenesis. In addition, the

construct does not necessarily disrupt a nuclear hormone receptor gene because it encodes at least two sequences that are homologous to a nuclear hormone receptor gene.

Inventions I and III are patentably distinct because the mouse of group III can be used as a model of disease while the construct can be used to transfect cells in vitro. The mouse does not require the construct and the construct do not have to be used to make the mouse. In addition, the construct does not necessarily disrupt a nuclear hormone receptor gene because it encodes at least two sequences that are homologous to a nuclear hormone receptor gene.

Inventions I and IV are patentably distinct because the construct can be used to make a probe while the method is used to make a disease model. The products and reagents required for a construct are materially distinct from those required to make a transgenic. Inserting the construct of claim 1 into a cell does not necessarily result in a disruption in the nuclear hormone receptor gene in claim 10. The construct of claim 1 encompasses a construct encoding the full-length gene. The method of claim 10 does not require disruption occurs. The burden required to search both groups together would be undue.

Inventions I and V are patentably distinct because the construct can be used to make nuclear hormone receptor or to disrupt a nuclear hormone receptor gene while modulators of nuclear hormone receptor can be used to treat disease. The protocols and reagents for constructs and modulators are materially distinct and separate. The

construct does not require the modulators and the modulators do not require the construct.

Inventions II and III are patentably distinct because the mouse of Group III can be used as a model of disease while the cells can be used to isolate protein in vitro. The mouse does not have to be made using a transfected cell or an ES cell as it may occur in nature. A cell comprising the construct may not disrupt a nuclear hormone receptor gene because the construct does not necessarily disrupt a nuclear hormone receptor gene.

Inventions II and IV are patentably distinct because the cells can be used to test compounds *in vitro* while the method is used to make an animal. The products and reagents required for the cells are materially distinct from those required to make a transgenic. Inserting the construct of claim 1 into a cell does not necessarily result in a disruption in the nuclear hormone receptor gene because the construct of claim 1 encompasses a construct encoding the full-length gene. The method of claim 10 does not require disruption occurs. The burden required to search both groups together would be undue.

Inventions II and V are patentably distinct because the cells can be used to study the function of nuclear hormone receptor while the nuclear hormone receptor modulators can be used to treat disease. The protocols and reagents for cells and modulators are materially distinct and separate. The cells do not require the modulators and the modulators do not require the cells.

Inventions III and IV are patentably distinct because the mouse can be used to make cells for an *in vitro* assay while the method is used to make an animal. The products and reagents required for the using the transgenic are materially distinct from those required to make a transgenic. The burden required to search both groups together would be undue.

Inventions III and V are patentably distinct because the mouse can be used as a model of disease while the modulator of nuclear hormone receptor can be used to treat a patient. The protocols and reagents for mice and for using a modulator to treat disease are materially distinct and separate. The mouse does not require the modulator and the modulator does not require the mouse.

Inventions IV and V are patentably distinct because the method can be used make a transgenic while the modulator of nuclear hormone receptor can be used to treat a patient. The protocols and reagents for making transgenics and for using a modulator to treat disease are materially distinct and separate. The method does not require the modulator and the modulator does not require the method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for each of the groups is mutually exclusive, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER